MAR - 7 2001 K003758

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the Sulzer Orthopedics Allofit Acetabular System.

Manufacturer:	Sulzer Orthopedics Ltd. Grabenstrasse 25 CH-6341 Baar, Switzerland
US Designated Agent:	Sulzer Orthopedics Inc. 9900 Spectrum Drive Austin, Texas 78717 (512) 432-9900
Date:	December 6, 2000
Contact Person:	Mitchell A. Dhority, RAC Manager, Regulatory and Clinical Affairs
Classification Name:	21 CFR Part 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (Shells, Inserts) 21 CFR Part 888.3330 - Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis (Metasul Insert only)
Common/Usual Name:	Nonporous, press-fit acetabular shell/insert system
Trade/Proprietary Name:	Sulzer Orthopedics Allofit Acetabular System

PRODUCT DESCRIPTION

Cementless hemispheric cups have enjoyed much clinical success over the last decade. One of the main reasons for this is that they imitate the original shape of the acetabulum and thus require minimal bone resection. As a result, it is possible to retain and use the subchondral bone bed as a load bearing element.

The Allofit System features a metallic hemispheric shell design that is "flattened" at the pole, thus preventing rocking at the zenith of the shell and allowing for more even load distribution at the periphery. In order to achieve primary stability and seating of the implant, the shell is 2mm larger than the reamed acetabulum. The shell locks in position mainly in the area of the subchondral bone layer, which not only serves as anchorage for the implant, but also continues to fulfill its original load bearing function.

The Allofit Acetabular System is offered in a variety of shell and insert configurations which use these same design principles.

I. Acetabular Shells

The Allofit Acetabular Shells come in two versions: Allofit and Allofit-S+. Both versions are identical with the only difference being that the Allofit-S+ has supplemental screw holes where the Allofit does not.

A. Allofit

This hemisperic shell is made of unalloyed titanium (Protasul-Ti, ISO 5832/2 grade 1) and is available in 10 sizes. Press-fit fixation (e.g., cementless) to the bone is achieved through the fine "teeth" arranged in concentric circles around the implant. Since the shell is oversized by 2mm at the periphery and undersized by 1mm at the pole, stable primary fixation is achieved at the equator. The toothlike macrostructure reinforces the binding effect on the subchondral bone and creates additional rotational control. The outer surface of the shell also possesses a roughened surface.

The inner surface of the shell is smooth and features a locking mechanism around the periphery for attachment of one of the Allofit Acetabular Inserts offered with the system. Two short spikes made of wrought CoNiCrMo alloy (Protasul-10, ISO 5832/6) positioned in the dome of the shell minimally penetrate the insert upon impaction. While these spikes do not "lock" into the polyethylene, they do provide additional rotational stability of the insert once the peripheral insert/shell locking mechanism is engaged. A polar dome hole in the shell interfaces with the peg shaped eminence on the apex of the inserts for further stability.

A polar domehole plug (Protasul-Ti, ISO 5832/2 grade 1) may also be used to prevent unwanted ingress/egress of particles or materials.

B. Allofit-S+

As previously mentioned, this shell is identical to the Allofit; the only difference is the addition of supplemental screw holes. The number of holes may vary slightly based on the shell diameter.

II. Inserts

Six insert options are available for use with the Allofit Shells: Alpha Standard Polyethylene (PE), Alpha Hooded PE, Alpha Standard Metasul, Alpha Hooded Metasul, Alpha Standard Durasul and Alpha Hooded Durasul. The inserts serve to form the articulation point between the femoral head and the acetabular shell component.

A. Alpha Standard and Hooded PE Inserts

Alpha standard and hooded polyethylene ("PE") inserts are available (Sulene-PE, ISO 5834). The inserts are snapped into the respective Allofit titanium shell intraoperatively. A peripheral locking mechanism holds the insert within the shell. A peg shaped eminence at the apex of the insert slips into the dome hole of the shell and provides further stability of the insert within the shell. Upon impaction into the shell, two short spikes in the dome of the metallic shell minimally penetrate

the polyethylene insert, providing additional resistance to rotation.

Both inserts are identical except that the hooded insert provides a 10° hood that can be positioned to provide resistance to subluxation/dislocation. The inserts will initially be available in 22, 28 and 32mm inner diameters and outer diameters.

B. Alpha Standard or Hooded Metasul Inserts

Alpha standard or hooded Metasul inserts are available in 11 outer diameters and 1 inner diameter (28mm). They are identical to the Allofit Alpha Standard and Hooded PE inserts except that they feature a cobalt-chrome metallic inlay (Protasul-21WF, ISO 5832-12) within the inner diameter of the polyethylene (Sulene-PE, ISO 5834). This Metasul metal inlay is identical to that which was previously characterized and cleared for use with the Inter-Op Acetabular System (K974728, K001536) and APR Acetabular System (K993569).

The Allofit Metasul inserts will use the same previously approved 28mm Metasul Femoral Heads.

C. Alpha Standard or Hooded Durasul Inserts

Alpha standard or hooded Durasul inserts (ISO 5834) are also available. They are identical to the Allofit Alpha Standard and Hooded PE inserts except that they utilize the Durasul material. The Durasul material is identical to that which was previously characterized and cleared for use with the Inter-Op Acetabular System (K983509, K993259, K002575). The inserts will initially be offered in only one inner diameter (28mm) and various outer diameters.

Previously cleared 28mm femoral heads will be used with these inserts.

SPECIFIC DIAGNOSTIC INDICATIONS

The Allofit Acetabular System is intended for press-fit use in treatment of the following:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed hip arthroplasty.

SUBSTANTIAL EQUIVALENCE

The Allofit Acetabular System is similar to the following commercially available devices in terms of intended use, general design and indications for use:

- Howmedica Osteonics Trident Acetabular System
- Howmedica Osteonics Osteolock Acetabular System

Testing/analysis indicated that the device would survive physiologic loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2001

Mr. Mitchell A. Dhority, RAC
Manager, Regulatory & Clinical Affairs
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K003758
Trade Name: Allofit Acetabular System
Regulatory Class: III
Product Codes: KWA, LZO
Dated: December 6, 2000
Received: December 6, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Mr. Mitchell A. Dhority, RAC

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003758

Device Name: Allofit Acetabular System

Indications for Use:

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2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed hip arthroplasty.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003758

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the Counter Use** ____